



UNITED STATES DEPARTMENT OF COMMERCE
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H.B.

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/025,363 | 02/18/98 | MARK | P97.1036 |

HM12/0914

HILL & SIMPSON
85TH FLOOR SEARS TOWER
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EXAMINER
SHARAREH, S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1616 | |

DATE MAILED: 09/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/025,363

Applicant(s)
David Mark et al

Examiner
Shahnam Sharareh

Group Art Unit
1616



☒ Responsive to communication(s) filed on 2/18/98, and 7/19/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Applicants Arguments for Claim Rejections - 35 USC § 102

Applicant's arguments and the newly amended claims filed on 7/19/99 have been fully considered but they are not found to be persuasive.

In contrary to Applicant's assertion that Schmidl et al does not anticipate the claimed invention, Examiner responds that Schmidl et al clearly disclose compositions comprising a protein component providing 16-25% of the total calorie of the formula, a lipid and a carbohydrate source wherein the protein content further comprise partially hydrolyzed protein.

Since the terms "Calorie", "Calories" or "Kilocalories" have been interchangeably used in the art, Schmidl's composition inherently possesses a caloric density of one Kilocalorie per milliliter. In addition, when a patent contains a range that varies from the parameter in a prior art, "the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *Woodruff*, 919 F.2d 1578 [16 USPQ2d 1934] see also *In re Ornitz*, 351 F.2d 1013 [147 USPQ 283] (C.C.P.A. 1965). It is also well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33 (C.C.P.A. 1937). *In re Russell* 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Therefore, Examiner adheres to the rejection that was made in the Office Action 4/28/99, because Schmidl et al disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of

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the formulation, wherein said protein source comprise a protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al further disclose a method for administering said formulation to a patient via various tube-feeding techniques (see Col 7 lines 60-67).

Therefore, for the above stated reasons, said claims are properly rejected under 35 U.S.C § 102, and therefore, the rejection is adhered to.

Response to Applicants Arguments for Claim Rejections - 35 USC § 103

Applicant's arguments and the newly amended claims filed on 7/19/99 have been fully considered but they are not found to be persuasive. In response to applicant's argument that the Patent Office "cannot pick and choose among the individual elements of assorted prior art references to create the claimed invention" and "the prior art must suggest the desirability of a modification", Examiner replies that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the

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instant case, Granger et al clearly discuss the advantages of using hydrolyzed protein sources in hypermetabolic patients; further, Schmidl et al disclose an enteral composition comprising suitable sources as well as concentrations of protein, lipid and carbohydrate for treating stressed and catabolic patients. In addition, the fact that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991): Contrarily, the abundance of various reference; in this case, the teachings of Cope et al '872 and Gray et al, would motivate one ordinary skilled in art to best determine what combination of nutritional elements could optimize an already marketed product such as Traumacal to suit the needs of metabolically stressed patients. Additionally, the Traumacal brochure and Schmidl et al indicate the adequate range of non-protein calories per gram nitrogen ratio for various hypermetabolic states (Traumacal brochure p. 36 B00143, last paragraph, and US Patent 5,504,072 see col 4 lines 1-5.); as do Gray et al '472 and Cope et al '872 the desired caloric content of a preferred formulation (see US Patent 5,714,472 col 3 lines 49-52, and US Patent 5,480,872 col 5 lines 15-18.)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072 and Gray et al 5,714,472 for the reasons set forth in the Office Action mailed 4/28/99.

Although the protein content of Gray's formulation does not provide 15 to 20 percent of its total calories, for the same reasons set forth in the Office Action mailed 4/28/99, one skilled in the art would have been motivated, from the teachings of Schmidl, to optimize the enteral formulation of Gray et al to meet the protein requirements of metabolically stressed patients without elevated protein levels or excess fluid.

For the above stated reasons, said claims are properly rejected under 35 U.S.C § 103, and therefore, the rejections are adhered to.

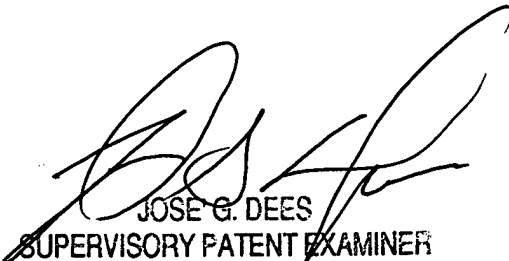
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sharareh whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjb 8/20/99


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616